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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

ROARK, JESSICA H

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 06/18/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/646,561

Applicant(s)

SIM ET AL.

Examiner

Jessica H. Roark

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1644

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 4/4/03 (Paper No. 20), is acknowledged.
Claims 1-3, 6, 8, 10-14, 16-19, 21, 23, 25-27 and 37-39 have been cancelled.
Claims 4-5, 7, 9, 15, 20, 22, 24 and 28-36 have been cancelled previously.
Claims 40-61 have been added and are under consideration in the instant application.
2. This Office Action will be in response to applicant's arguments, filed 4/4/03 (Paper No. 20).
The rejections of record can be found in the previous Office Action (Paper No. 19).
It is noted that New Grounds of Rejection are set forth herein.
3. Applicant's comments in the Remarks filed 4/4/03 that the cancellation of claims 1-3, 6, 8, 10-14, 16-19, 21, 23, 25-27 and 37-39 has obviated the previous objections and rejections with respect to these claims are acknowledged.

Priority

4. Applicant's claims for domestic priority under 35 U.S.C. 119(e) and 35 U.S.C. 120 are acknowledged.

The Examiner maintains the following assessment of priority based upon provisional application 60/078,765 (filed 03/19/1998) and U.S.S.N. 09/062,597 (filed 04/17/1998):

<u>instant claims</u>	<u>'597</u>	<u>'765</u>
canine B7-2 of SEQ ID NOS:6, 8-10	yes	yes
soluble canine B7-2 of SEQ ID NOS:16, 18-20	yes	yes
feline B7-2 of SEQ ID NOS: 25, 27-29	yes	no
PCR clone 1 of SEQ ID NOS:30 and 32	no	no
PCR clone 2 of SEQ ID NOS:33 and 35 (partial soluble)	no	no
canine B7-2 function of T cell proliferation	yes	no
feline B7-2 function of CTLA4 binding	no	no

Claim 41 lacks adequate written support in the priority documents for the same reasons as set forth below in the rejection under 35 USC 112, first paragraph, written description.

Thus neither provisional application 60/078,765 (filed 03/19/1998) nor U.S.S.N. 09/062,597 (filed 04/17/1998) provides adequate support under 35 U.S.C. 112 for claims 40-61 of this application.

Thus the effective filing date of the instant claims is considered to be the filing date of the instant application, i.e., 3/19/1999.

IDS

5. Applicant's IDS, filed 6/24/02 (Paper No. 12), is again acknowledged.

Applicant is thanked for providing a second copy of IDS reference A2, which has now been considered as indicated on the attached copy of from PTO-1449.

Art Unit: 1644

Claim Objections

6. Claim 57 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim, claim 56. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form.

7. Claims 46, 50, 55 and 59-61 are objected to under 37 CFR § 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Even though these claims are in improper form, the examiner has chosen to examine claims.

8. Claim 43 is objected to for the following informalities: there is an extra period following the “and” that links sections (a) and (b), but no period following section (b). Appropriate correction is required.

Claim Rejections - 35 USC § 112 second paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 43, 53, 54 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) There is lack of antecedent basis for the SEQ ID NOS encoding non-soluble B7-2 proteins in claim 43 because claim 41, from which claim 43 depends, requires that the nucleic acids encode a soluble B7-2 protein.

B) Claims 53, 54 and 55 each recite the method of claim 50. However, claim 50 recites a composition. Therefore there is a lack of antecedent basis for claims 53, 54 and 55 as currently recite. It appears that the claims were intended to depend from claim 51, and will be so interpreted for examination purposes.

C) Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

Claim Rejections - 35 USC § 112 first paragraph

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1644

12. Claims 40-46, 50-55 and 59-61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The following *written description* rejection is set forth herein.

The claims recite:

- A) a nucleic acid that is at least about 95% identical to reference sequences, but lacks functional limitations,
- B) "allelic variants" of nucleic acids, and
- C) a genus of nucleic acids encoding "naturally-occurring (soluble) canine or feline" B7-2 proteins.

Applicant's Remarks, filed 4/4/03, have been full considered as they apply to the amended claim language. Applicant's Remarks are addressed below in the context of the rejections as applied to the newly submitted claims.

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

Regarding the instant claim limitations, the specification does not appear to provide an adequate written description for the following reasons:

A) "Percent Identity":

The claims recite a genus of nucleic acid molecules which differ in sequence to varying extents from the recited nucleic acids. The claims do not require that the instant nucleic acids share any testable functional activity of the polypeptides encoded by the instant nucleic acids, a feature deemed essential to the instant invention. Applicant has disclosed only canine and feline B7-2, and a soluble variant of each and thus has disclosed only a limited number of species. However, the instant claims are drawn to an extensive genus of nucleic acids. In the absence of a particular testable function and some structural basis for that function that must be maintained by the members of the genus, the claimed invention is not described in such a way as to reasonably convey to one of ordinary skill in the art that the inventor, at the time the application was filed, had possession of the invention. See Regents of the University of California v. Eli Lilly & Co., 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Applicant is also directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant's Remarks that the newly added claims now provide a testable function coupled with only limited sequence variation (95% identity) are acknowledged. Although many of the claims do now recite a testable function, claims 51-52 do not.

Art Unit: 1644

B) "Allelic Variants":

As previously noted in Paper No. 19, the term "allelic variants" encompasses any gene that occurs at essentially the same locus in the genome as the reference gene, as disclosed in the specification as-filed on page 14, lines 1-5. However, there is insufficient written description in the specification of such allelic variants of B7-2. First it is noted that there is no written description of genomic DNA in the specification: the instant SEQ ID NOS are derived from cDNA libraries. cDNA does not provide an adequate written description of genes and allelic variants thereof because no information is provided as to whether the genomic DNA has introns, where said introns are located, etc.

The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 USPQ2d 1016 (Fed. Cir. 1991).

Applicant's Remarks that the newly submitted claims include a testable function are acknowledged.

However, even when a testable function is recited, the claims still do not provide an adequate written description of the claimed subject matter because there is no nexus between the recited function and a structure: an allelic variant is any gene that occurs at that locus, irrespective of the structure of the encoded protein. Thus the term "allelic variant" fails to provide a structure for which a function can be correlated, and in the absence of additional support in the specification as filed, the term "allelic variant" does not meet the written description provision of 35 U.S.C. 112, first paragraph.

C) Nucleic acids encoding "naturally-occurring (soluble) canine or feline" B7-2 proteins:

As noted previously, the specification discloses SEQ ID NOS:16 (full length) and 19 (coding), nucleic acids encoding a naturally-occurring soluble canine B7-2 protein; and SEQ ID NO: 33, a partial sequence for a nucleic acid encoding a naturally-occurring soluble feline B7-2 protein. Thus the specification provides at most two members of the instant genus of any nucleic acid encoding "naturally-occurring (soluble) canine or feline" B7-2 proteins.

The specification further discloses a naturally-occurring canine B7-2 protein as set forth in SEQ ID NO:6 (full length) and SEQ ID NO:9 (coding), and a feline B7-2 protein as set forth in SEQ ID NO:25 (full length) and SEQ ID NO:28 (coding). Thus the specification provides at most four members of the instant genus of any nucleic acid encoding "naturally-occurring canine or feline" B7-2 proteins.

In University of California v. Eli Lilly and Co., 39 USPQ2d 1225 (Fed. Cir. 1995); the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The Court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, *id.* at 1240.

Applicant's Remarks that the newly submitted claims are limited to only canine and feline, rather than all mammalian, proteins is acknowledged. However, even though the genus is not as large as "any mammalian", the claims are nevertheless drawn to *any* feline (i.e., domestic cats as well as many diverse wild species) or *any* canine (i.e., domestic dogs as well as any number of wild canine species) for which Applicant has described only a limited number of members.

Therefore, the specification does not provide sufficient written support for the genus of nucleic acids encoding "naturally-occurring (soluble) canine or feline" B7-2 proteins, irrespective of the inclusion of functional limitations. A description of what a material does, rather than of what it is, usually does not suffice. Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.

Art Unit: 1644

The specification thus fails to provide an adequate written description of the above noted claim limitations.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Alternatively, Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

13. Claims 40-46, 50-55 and 59-61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated nucleic acids comprising SEQ ID NOS:6, 8-10, 16, 18-20, 25, 27-30, 32-33 and 35; nucleic acids encoding proteins comprising SEQ ID NOS:7, 17, 26 and 34; nucleic acids encoding proteins that stimulate T cell proliferation and at least about 95% identical to a reference sequence; does not reasonably provide enablement for

A) a nucleic acid that is at least about 95% identical to reference sequences, but does not necessarily encode a protein that stimulates T cell proliferation,

B) "allelic variants" of nucleic acids, and

C) a genus of nucleic acids encoding "naturally-occurring (soluble) canine or feline" B7-2 proteins.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant's Remarks, filed 4/4/03, have been full considered as they apply to the amended claim language. Applicant's Remarks are addressed below in the context of the rejections as applied to the newly submitted claims.

The specification discloses nucleic acids encoding canine and feline B7-2, either as nucleic acids including 5' and 3' untranslated regions (SEQ ID NO:6, canine; SEQ ID NO:25, feline), or as limited to coding regions (SEQ ID NO:9, canine; SEQ ID NO:28, feline), and the full length complements of each of these nucleic acids (SEQ ID NOS:8 and 10, canine; SEQ ID NOS:27 and 29, feline). The specification also discloses cDNA encoding a full length canine soluble B7-2 protein in which the transmembrane domain has been deleted (SEQ ID NOS: 16 and 19 (coding region)), and the full length complements of said nucleic acids (SEQ ID NOS: 18 and 20). A PCR clone containing a cDNA of a partial feline soluble B7-2 is also disclosed (SEQ ID NO: 33) and the full length complements of said nucleic acids (SEQ ID NO:35). Finally, the specification discloses a PCR clone of a feline cDNA corresponding to a portion of the full length sequence (SEQ ID NO:30 and SEQ ID NO:32, full length complement).

The specification discloses that the canine B7-2 protein when transfected in CHO cells will stimulate resting T cells (i.e., functions to costimulate T cell proliferation, Example 4 pages 59-60).

Art Unit: 1644

A) "Percent Identity":

Applicant's Remarks that the newly added claims now provide a testable function coupled with only limited sequence variation (95% identity) are acknowledged.

Although many of the claims do now recite a testable function, claims 51-52 do not. Thus for the reasons set forth in full in Paper No. 19, there appears to be insufficient guidance in the specification as filed with respect to how to make and use the nucleic acids of newly added claims 51 and 52 because there still is no requirement that the variant nucleic acid sequence possess a testable function.

B) "Allelic Variants":

Applicant argues in the Remarks filed 4/4/03 that undue experimentation would not be required of the skilled artisan to use the teachings of the specification to identify allelic variants and test them for the instantly recited function.

As previously noted in Paper No. 19, the term "allelic variants" encompasses any gene that occurs at essentially the same locus in the genome as the reference gene, as disclosed in the specification as-filed on page 14, lines 1-5. For the reasons set forth supra, the specification still does not appear to provide an adequate written description of "allelic variants" of the instant sequences; thus the specification fails to provide sufficient guidance as to how to make allelic variant sequences. In addition, allelic variants do not necessarily encode proteins having the same function. For example, Voet et al. (In Biochemistry. John Wiley & Sons. 1990, Vol.1, pages 126-128, and page 230, of record) teaches that allelic variation in the β subunit of hemoglobin results in drastically different functions, even though the proteins share a high level of sequence and structural homology. Thus even had the specification clearly taught how to make allelic variants of the instant sequences, the skilled artisan still would not know how to use them. Consequently, the scope of claims reciting "allelic variants" does not appear to be commensurate with guidance provided in the specification as filed, and it would require undue experimentation of the skilled artisan to make and use such nucleic acid sequences.

C) Nucleic acids encoding "naturally-occurring (soluble) canine or feline" B7-2 proteins:

Applicant notes in the Remarks filed 4/4/03 that the newly submitted claims have been limited to nucleic acids encoding "naturally-occurring (soluble) B7-2 proteins" that are either canine or feline.

However, there is still insufficient biochemical or structural information to enable the skilled artisan to make and use a nucleic acid encoding any "naturally-occurring soluble canine or feline" B7-2 protein, as broadly claimed. The breadth of the instant claim still encompasses any nucleic acid that encodes a B7-2 protein that is soluble for *any* reason (e.g., lacking a transmembrane domain only, lacking all sequence at the carboxy terminus, lacking all domains except the IgV domain, etc.).

Neither does the specification appear to provide sufficient guidance as to which epitopes must be conserved between the variant nucleic acids and any "naturally-occurring canine or feline B7-2 protein" such that the skilled artisan could select the variants of the instantly recited nucleic acids which would encode a protein that elicited an immune response against the "naturally-occurring" protein without undue experimentation. The structure of a "naturally-occurring" canine or feline B7-2 protein is not limited to the instantly disclosed proteins, but instead encompasses any protein that may exist in any feline or canine that can be considered by some undefined criteria to be a "B7-2" protein. As noted supra, numerous species are encompassed within the terms "canine" and "feline" besides domestic cats and dogs.

The instant claims are essentially a wish to know the identity of any nucleic acid meeting these general parameters. It has been previously decided that claims recitations so broad do not provide sufficient guidance as to how to make and use the claimed invention. See Colbert v. Lofdahl, 21 USPQ2d, 1068, 1071 (BPAI 1992).

Art Unit: 1644

Thus with respect to these claim limitations, each of which encompasses considerable breadth and for each of which the specification provides only limited guidance; it would require undue experimentation of the skilled artisan to make and use such nucleic acid sequences; thus the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

35 U.S.C. §§ 102 and 103

14. The following rejections under 35 U.S.C. §§ 102 and 103 are made under the assumption that the effective filing date of the instant claims is the filing date of the instant application, i.e., 3/19/1999.

It is again noted that claims *limited to canine B7-2 sequences* would appear to be entitled to an earlier effective filing date that would obviate certain rejections set forth below.

Claim Rejections – 35 U.S.C. §§ 102 and 103

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. Claims 40, 44, 46-52 and 55-61 are rejected under 35 U.S.C. 102(e) as being anticipated by Collisson et al. (US 2002/0028208 A1, of record, see entire document).

Applicant has argued in the Remarks filed 4/4/03 that Collisson et al. is not available as a reference under 35 USC 102(e) because it was filed on April 30, 1999.

Art Unit: 1644

However, the effective US filing date of Collisson et al. appears to be May 1, 1998 in view of the priority claimed under 35 USC 119(e) to provisional application 60/083,869. Therefore, Collisson et al. is available as a reference under 35 USC 102(e) as of May 1, 1998.

As previously noted, Collisson et al. teach the nucleic acid of SEQ ID NO:5 (see e.g., sequence listing). SEQ ID NO:5 is a nucleic acid encoding a feline B7-2 protein (see entire document, e.g., paragraph 28 and Figure 3A).

SEQ ID NO:5 of Collisson et al. is an isolated nucleic acid which is a coding region that is 98% identical to the coding region set forth in SEQ ID NO:28, and is therefore also 98% identical to the coding region (residues 179-1174) of SEQ ID NO:25.

The protein encoded by SEQ ID NO:5 is also at least about 95% identical over its full length to instant SEQ ID NO:26. The encoded B7-2 protein would also inherently elicit an immune response against a naturally-occurring B7-2 protein or stimulate T cell proliferation.

The complement of SEQ ID NO:5 is also taught (e.g., paragraph 70).

The isolated nucleic acid of Collisson et al. set forth in SEQ ID NO:5 can also be considered an allelic variant of at least SEQ ID NOS: 25 and 28, since each encodes a feline B7-2 protein but differ from each other by a few nucleotide residues.

Collisson et al. also teach fragments of the nucleic acid that are at least about 12 nucleotides (e.g., paragraph 37). SEQ ID NO:38 is a fragment that is at least about 18 nucleotides and that is found in each of instant SEQ ID NOS:6, 9, 16, 19, 25 and 28 (e.g., at about positions 392-416 of SEQ ID NO:9).

Collisson et al. also teach formulation of the nucleic acid of SEQ ID NO:5 in compositions to regulate T cell immune responses (e.g., paragraphs 59, 94 and 103-106). Formulations including excipients, adjuvants and carriers are also taught (e.g., paragraph 106), as are both naked nucleic acid vaccines and a recombinant cell vaccine (e.g., paragraphs 73, 94 and 103-104).

Collisson et al. also teach linking the nucleic acid of SEQ ID NO:5 to transcription control sequences, and recombinant cells and viruses comprising said nucleic acid and methods of producing a B7-2 protein (e.g., paragraphs 70-74).

Finally, Collisson et al. teach nucleic acids encoding soluble feline CD86 lacking the transmembrane domain (e.g., paragraphs 44 and 55). It is noted that the B7-2 protein encoded by the nucleic acids of Collisson et al. would inherently be soluble, bind either or both of CD28 and CTLA4 and would deliver a co-stimulatory signal to a helper T cell sufficient to stimulate cytokine secretion (see also paragraphs 54-55).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the nucleic acid of SEQ ID NO:5.

The reference teachings thus anticipate the instant claimed invention.

Art Unit: 1644

Conclusion

17. No claim is allowed.

18. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
June 13, 2003

Phillip Gambel
PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
Tech Center 1600
6/13/03